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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,680	11/29/2000	Ryuzo Hosotani	YANAGIHARA	7997

7590 02/26/2003

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EXAMINER

WHITE, EVERETT NMN

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/701,680

Applicant(s)

HOSOTANI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The amendment filed December 9, 2002 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) A new abstract has been provided. The abstract is proper.
  - (B) Claims 1-6 have been canceled.
  - (C) New Claims 7-14 have been added.
  - (D) Comments regarding Office Action have been provided drawn to
    - (a) 112 2<sup>nd</sup> paragraph rejection, which has been withdrawn.
    - (b) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.
2. Claims 7-14 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 103***

4. Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiku et al (WO 98/09650) or Macromolecules, 3062 (1993) in view of Lander (US Patent No. 6,410,025) or Okumura et al (US Patent No. 5,272,053).

Applicants claim a process for forming aggregates of hydrophobic group-containing polysaccharide comprising the steps of: mixing the hydrophobic group-containing polysaccharide with water in an amount of 30-10,000 times the weight of the hydrophobic group-containing polysaccharide to form a swollen dispersion of the hydrophobic group-containing polysaccharide and treating the swollen dispersion of the hydrophobic group-containing polysaccharide with a homogenizer under a pressure of from 9.8-490 MPa to form a dispersion of monodisperse aggregates of the hydrophobic group-containing polysaccharide. Additional limitations of the claimed invention include the use of a high-pressure homogenizer, particle size of aggregates, the aggregate number of association, a formula for hydrophobic groups, specific polysaccharides, and specific pressure ranges.

The instant specification on page 4, 2<sup>nd</sup> paragraph discloses that the Shiku et al WO patent and the Macromolecules reference disclose processes in which the

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hydrophobic group-containing polysaccharide is caused to swell in water and the resulting swollen dispersion is then treated by ultrasonication. See the abstract of the Shiku et al WO patent for the disclosure of a formula of a hydrophobic group that may replace a hydroxyl group of the polysaccharide, which is similar to the hydrophobic group represented by formula (I) of instant Claim 11. Also, see lines 4 and 5 of the abstract disclosed in the Macromolecules reference wherein the diameter of the particles are  $25 \pm 5$  nm, which is within the particle size range set forth in instant Claim 10. The abstract also discloses an aggregation number of approximately 13, which is within the range of the aggregation number (or number of association) set forth in the instant claims. The abstract of the Macromolecules reference further indicates pullulan as the hydrophobized polysaccharide, which is also recited in instant Claim 12. The process of the instantly claimed invention differs from the process of the Shiku et al patent and the Macromolecules reference by claiming the use of a homogenizer to form the dispersion of monodisperse aggregates instead of treatment of the hydrophobic group-containing polysaccharide with an ultrasonicator.

The Lander patent shows that the use of a homogenizer in a procedure for preparing polysaccharides is known in the art. See column 3, lines 20-29 of the Lander patent wherein a reduced size, monodispersed polysaccharide is prepared by passage of the polysaccharide through a high-pressure orifice using a mechanical homogenizer. Example 1 of the Lander patent recites a homogenizer pressure of 3,000 to 14,000 psi which falls within the pressure range set forth in the instant claims.

The Okumura et al patent is cited to show that the interchangeability of a homogenizer with an ultrasonicator is well known in the art. See the paragraph bridging columns 25 and 26 wherein the dispersion of a hydrophobic compound in an aqueous solution may be carried out using any number of apparatuses that include a homogenizer and an ultrasonicator.

A person of ordinary skill in this art would be motivated to combine the teachings of the Shiku et al references with the Lander and Okumura et al patents in a rejection of the claims under 35 U.S.C. 103 since each reference discloses treatment of products using an apparatus to disperse the products to achieve a desired result.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the ultrasonicator used in the Shiku et al WO patent and the Macromolecules reference with the homogenizer disclosed in the Lander patent which interchangeability is further confirmed in the Okumura patent, in view of the recognition in the art, as evidenced by the Lander and Okumura patents, that dispersing products using a homogenizer is an effective means for preparing particles of reduced and uniform size.

5. Applicant's arguments with respect to Claims 7-14 have been considered but are moot in view of the new ground(s) of rejection.

#### **Summary**

6. All the pending claims are rejected.

#### **Conclusion**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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***Examiner's Telephone Number, Fax Number, and Other Information***

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

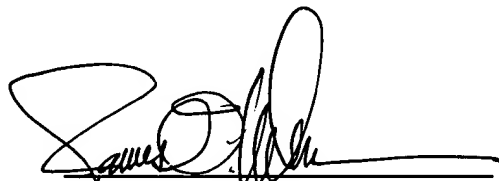
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E. White

  
James O. Wilson  
Supervisory Primary Examiner  
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